November 24, 1999

Dockets Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane
Room 1061
HFA-305
Rockville, MD 20852

Via regular mail

RE: Docket number 99D-4130

Dear Sir or Madam:

This letter is in response to the FDA's Guidance on Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems, docket number 99D-4130.

In order to present an accurate account, for the public, of what the issues involving disclosure of information by manufacturers are, I believe a background of where this issue began and where the issue is today is necessary.

On August 15, 1972 the FDA announced federal requirements for the disclosure for information by manufacturers of ionizing emitting devices to assemblers, users and others. During the course of the next several years the FDA announced additional requirements for disclosure of information to assemblers, users and others from manufacturers for ionizing emitting devices.

In the mid 1980's the FDA discovered that assemblers were not following manufacturers instructions as required by federal law, 21CFR section 1020.30(g). The FDA imposed fines and other possible punishment, 21U.S.C. 360(oo)(pp), against assemblers and others in order to correct and enforce the federal laws that the FDA is responsible for. However, the FDA apparently never investigated the manufacturers to assure the manufacturers of ionizing emitting devices were supplying this vital and required information before enacting new laws against assemblers.

In 1994, during the trial phase of my litigation with Picker International (Picker), certain FDA issues were made known to me in Picker testimony and documents that were previously sealed. I contacted the FDA's CDRH in October of 1994 with questions regarding Picker's obligations to comply with the federal laws the FDA is responsible for. I was informed by CDRH that this was the first time CDRH became aware that a manufacturer of ionizing emitting devices was not complying with the federal laws the FDA is entrusted to enforce.

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After extensive talks with CDRH and a growing understanding of the laws contained in 21 CFR section 1020.30-33, I placed two orders at Picker for compliant materials. The first order for compliant materials under 21CFR section 1020.30(h) Picker complied with. However, Picker denied my second request for compliant materials for all sections of 21 CFR.

In May of 1995, Picker filed a response Motion in the Federal Court in Boston, essentially denying all obligations under 21 CFR section 1020.30(g). The Court ruled in favor of Picker and issued a sweeping injunction on July 5, 1995 against my former company and myself. The FDA was informed of Picker's actions in a real time situation. The FDA did not act to protect the FDA's right to regulate medical devices or the federal laws the FDA is entrusted to enforce in regards to Picker activities.

In September of 1996, CDRH issued a letter to Picker directing Picker to comply with my request. CDRH directed Picker to comply with the laws contained in 21 CFR section 1020.30(g). Picker refused citing among other things the Boston Court Order.

In August of 1997, CDRH issued another letter to Picker to comply with the regulations contained in 21CFR per my request. CDRH specifically informed Picker that Picker's private litigation (Boston litigation) had no effect on Picker's responsibilities. Picker again refused to comply with CDRH's directive.

In December of 1997, CDRH issued a Guidance to the Industry letter on the responsibilities of manufacturers to disclose information to assemblers. This letter has had little or no effect on the manufacturers of ionizing emitting devices.

In October of 1999, CDRH issued the Guidance on Information Disclosure by Manufacturers to assemblers for Diagnostic X-ray Systems. In the month that this document has been available to manufacturers, I can say from my expert opinion, that this document has had little or no effect on the manufacturers of ionizing emitting devices.

I have reported various manufacturer reactions to this new Guidance document to CDRH during the past month. CDRH has not taken any action to correct this on going problem of manufacturers of ionizing emitting devices flagrant and willful violations of the federal laws the FDA is entrusted to enforce. Some of the problems reported for the various manufacturers since the latest Guidance document has been issued and on going practices are:

1. Picker is refusing to sell compliant materials for the mx8000 CT Scanner per 21 CFR section 1020.30-33.
2. Picker is not complying with the "upon request" requirement of 21 CFR 1020.30(g). Picker is relying on "pending litigation", Boston Court, as one of the reasons for these delays and self imposed practices.

3. Picker has not resolved the issue of my request of March of 1995 and the Boston Court order that infringes on the FDA's ability to regulate ionizing emitting devices.
4. It has been reported, by assemblers, that Picker's compliant materials are not adequate to assure compliance with the regulations contained in 21CFR section 1020.30(g)-33. Picker refuses to make available the necessary materials as detailed in Picker's Initial and Supplemental reports filings and designated for assemblers, users and others.
5. Picker is seeking expansion of the Boston Court's Order that would further violate the federal laws the FDA is entrusted to enforce.
6. The quality of Siemens Medical (Siemens) compliant materials is not in question. However, Siemens is still charging a yearly license fee for compliant materials far in excess of the regulations contained in 2 1 CFR section 1020.30(g)-33. Siemens is considering changes but I understand Siemens is waiting for the comment period of this Guidance document to end first.
7. General Electric Medical Systems (GEMS) has been one of the best manufacturers for complying with the federal laws contained in all sections 21 CFR. However, GEMS is requiring specificity for additional compliant materials beyond what I believe is possible or necessary by assemblers, users and others to complete compliant orders. GEMS is not answering these questions in a timely manner or in some cases not at all.
8. I have not had any current interfacing with Philips and Toshiba Medical Systems for compliant orders. However, both of these manufacturers have not been a serious problem in the past.

It is a well-established fact that the FDA has the responsibility to regulate and enforce the federal laws contained in 2 1 CFR concerning manufacturers, assemblers, users and others. The FDA is legally required to carry out its responsibility in a manner consistent with all federal laws contained in 2 1 CFR in a timely manner. The time line above suggests that this is not the case. Although my intent was not to single out any one manufacturer for criticism, the FDA cannot expect other manufacturers to cooperate with assemblers, users and others if one or more are not.

My recommendations are:

A. Require all manufacturers of ionizing emitting devices to include appropriate language in the original sales contract and in all sales literature that defines what the manufacturers responsibilities are under 2 1 CFR section 1020.30-33 and other sections including 1040 and 820.170 are to all purchasers.
B. Require all manufacturers of ionizing emitting devices to certify to the FDA that all Court actions undertaken by them do not infringe on the FDA's right to regulate devices. That any manufacturer's claims of trade secret, proprietary protection made to any Court are corrected to reflect the FDA's right to regulate these devices.
C. Require all manufacturers of ionizing emitting devices to have in place acceptable ordering systems to allow assemblers, users and others

unobstructed access to compliant materials as required by the federal laws contained in 21CFR section 1020.30-33, 1040 and 820.170.

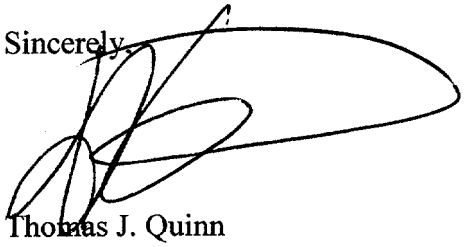
D. Require all manufacturers of ionizing emitting devices to make available the materials described in the Initial and Supplemental reports and designated as available to assemblers, users and others without any restrictions to assemblers, users and others. Additional materials must also be made available if needed by assemblers, users and others. All claims of trade secret or proprietary information by any manufacturer must be supported by fact and with the emphasis on the safety of these devices being of overriding importance to the FDA.

E. Define the costs of production and distribution to all manufacturers in a manner that the manufacturers cannot misinterpret.

F. Immediate and strong enforcement by the FDA for any manufacturer who defies the FDA's clear and unambiguous guidance on this issue. It is well known throughout the manufacturing community that the FDA is slow to act and overly sensitive to the manufacturers concerns. The FDA should show no mercy for any manufacturer, assembler, user or other who willfully violates these laws.

Thank you for your time in this matter.

Sincerely,



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